

any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD-1932. A separate "Adverse Drug Reaction" form should be submitted for each patient where feasible.

(c) In lieu of Form FD-1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD-1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD-1932 and FD-2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health and Human Services, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 41 FR 35844, Aug. 25, 1976; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

§ 510.305 Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location on the premises of each establishment to which an approved medicated feed application (Form FDA 1900) or supplemental application applies either:

(a) A copy of the approved medicated feed application (Form FDA 1900) and a sample of the approved labeling; or

(b) Identification of the approved medicated feed application in a single file or in a single readable document that includes:

(1) The application number and date of its approval;

(2) The name(s) of the premix(es) and the concentration of the drug(s) contained in the premix(es);

(3) The name(s) of the approved manufacturer(s) of the premix(es);

(4) The concentration of the drug(s) in the finished medicated feed; and

(5) A sample of the approved labeling.

[41 FR 36203, Aug. 27, 1976, as amended at 51 FR 7391, Mar. 3, 1986]

Subpart E—Requirements for Specific New Animal Drugs

§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]